

### REMARKS

Claims 1-83 were pending.

Claims 4, 5, 21-59, 71, and 74-83 have been cancelled.

Claims 60-69 and 72-73 have been withdrawn.

Claims 1, 2, 3, and 60 have been amended. Support for the amendments may be found in claims 2 and 61 and in the specification.

Claim 4 has been amended to incorporate the substance of claim 1 (upon which it depended) and claim 5 (which depended upon claim 4).

Claims 6, 7, 62-64, and 66 have been amended to correct dependency.

No new matter has been added by the amendments.

### Specification

The specification was objected to at several places.

The specification has been amended to recite the full, legal name of the entities, or to include the ® symbol.

In addition, Table I was objected to due to a typographical error ("T tal"). A replacement Table I has been provided with "Total" properly spelled.

No new matter has been added by these amendments

### §112 Rejections

Claims 1-20 and 71 have been rejected under 35 U.S.C. §112, second paragraph for use of the term "acceptable mouthfeel," while claim 71 has been rejected for using "no or only a slight detectable chalky mouthfeel."

Claim 1 has been amended to remove the objected-to words, and claim 71 has been cancelled. No new matter has been added by the amendments.

Claims 10-12 have been rejected under 35 U.S.C. §112 for use of the term "total specific surface area." However, total specific surface area of PSD is a term known to one of skill in the

art. For example, the specific surface area may be calculated from the PSD curve – such as by summing the area under the curve, or by using analytical expressions. The attached pages show a calculation page presented at a Technical Seminar for a particle size analyzer, as well as pages from the manual for the Horiba LA-910 Analyzer wherein S.P. area is defined as representing the specific surface area. In addition, the attached Kluetz declaration specifically includes attached test results for sample CG-522 (Table I). The printout reports SP Area of 39,644  $\text{cm}^2/\text{cm}^3$  (convert to reported results of 4.4  $\text{m}^2/\text{g}$  by dividing by 1000  $\text{cm}^2$  per  $\text{m}^2$ , and dividing by sterol density of approx. 0.92  $\text{g}/\text{cm}^3$ )

Accordingly, this rejection should be withdrawn.

### **§103 Rejections**

Claims 1-20 and 70-71 have been rejected under 35 U.S.C. §103(a) over Tiainen (US 6,129,944) in view of Lerchenfeld (US App. 2003/0232118), Haarasilta (WO 98/58554) and Anderson (Journal of Nutrition).

Tiainen does not describe, teach or show a particle distribution having the peaks as claimed. Furthermore, Tiainen teaches that problems may arise when using a composition having a distribution of very small particles and larger particles.

**Different Distribution Peaks.** Tiainen discusses a microcrystalline plant sterol that has a particle size distribution with two peaks in the distribution. This may also be more clearly seen by referring to the graphs in Tiainen. However, as can be seen, Tiainen does not show a peak amount of particles having a diameter less than 2 microns, as both peaks occur at sizes greater than 2 microns. Furthermore, Tiainen also does not show a peak of material having an average diameter of 8-12 microns, as the peaks of Tiainen are both at diameters less than 8 microns.

In contrast, amended claim 1 recites “a) a first peak of particulate plant sterols having a diameter less than 2 microns; and b) a second peak of particulate plant sterols having a diameter in the range from 2 to about 35 microns, wherein said second peak has a volume-weighted mean particle diameter of about 8 to about 12 microns.” Independent claims 4 and 70 have similar

language. This may be more clearly seen by referring to the printout from a Horiba LA-910 analyzer, as attached to the submitted Kluetz Declaration. The printout clearly illustrates an example composition having peaks as claimed.

**Product Problems due to Distribution.** Importantly, Tiainen teaches that a distribution including both very small particles and large particles causes technical problems as well as problems with taste and structure when added to edible products (col. 3, lines 4-21). The broad distribution of the non-pulverized sample is compared to the more homogeneous distribution of the processed material (Ibid.). One of the non-processed samples referred to as being problematic includes 90% of the material having a diameter less than 25 microns, and 95% of the material having a diameter less than 30 microns (FIG. 1, lines 2 and 4).

From the discussion in Tiainen, one of skill in the art would understand that Tiainen teaches that the distribution should be fairly homogeneous and not include both very small particles and larger particles. As this teaching is opposite to the composition as claimed (which includes very small particles and larger particles in distinct peak amounts), the rejections over Tiainen should be withdrawn.

**Other References.** In addition, none of the additional cited references makes up for the missing peaks of Tiainen or overcomes the Tiainen teaching towards a more homogenous distribution. Lerchenfeld shows a volume-weight distribution of sterols. However, the distributions shown are not multi-peak, as is required by the claims. Rather, the graphs show a generally normal, *single-peak*, distribution of points (though it is presented as a series of bar graphs rather than a line chart). This is also expressly stated in Lerchenfeld in paragraph [0026] that the dispersions will “substantially follow a bell curve distribution.” The normal or bell curve distribution is a single peak distribution, and not a multi-peak distribution. As Lerchenfeld does not demonstrate the required multi-peak distribution, it cannot be combined with Tiainen’s multi-peak distribution in a meaningful manner.

Anderson and Haarasilta may discuss general uses of sterols, but they do not discuss or show any particular distributions. Therefore, they cannot make up for the deficiencies discussed above.

**Analysis.** The Examiner presents a series of statements that the distribution as claimed would be obvious, but presents no meaningful arguments or support for such a conclusion. As described above, Tiainen itself teaches a method and a resulting composition that does not meet either portion of the claimed composition and none of the other references cited make up for this deficiency. There is no suggestion or teaching in Tiainen that a distribution other than that shown by Tiainen would be desirable or even possible. Thus, one of skill in the art would have no expectation of success that a significantly different distribution would result from following Tiainen, much less a distribution as claimed which has peak amount of material both smaller and larger than the peaks in Tiainen.

Furthermore, Tiainen teaches that a combination of very small and larger particles causes problems. Therefore, one of skill in the art is taught towards using a more homogeneous distribution and away from a less homogeneous dispersion with greater separation between peaks (as is claimed).

The improper basis for the obviousness rejection can be shown by summarizing the Graham Factors:

1) *Prior Art.* The prior art includes a multi-peak distribution including two peaks between 2 and 8 microns (Tiainen) and another showing a normal distribution of sterols (Lerchenfeld).

2) *Differences.* The claims cover a multi-peak distribution (as opposed to single peak of Lerchenfeld). The claimed distribution peaks includes both one peak having a size smaller than any measured amount of sterols in Tiainen, and another peak having a particle size greater than any peak of the Tiainen processed material distribution. Thus, the claims are not merely an optimization of the Tiainen distribution, but are rather an entirely different distribution than that found in Tiainen.

For the above reasons, the obviousness rejection is not fully articulated and well-supported, as is required. Furthermore, the rejection ignores Tiainen's teachings away from a

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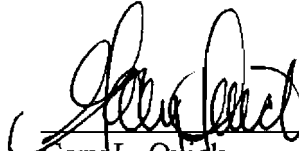
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combination of very small and larger particles. Accordingly, applicants request that the obviousness rejection be withdrawn.

If it would be helpful to prosecution, the Examiner is invited to contact the undersigned at the listed number. No fees are believed to be due. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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